Remarks

The Office Action incorrectly states that claims 1-22 are pending in the application. Claims 1-23 are pending in the application. The claims as originally filed were misnumbered. The proper number of claims were listed and acted upon by the examiner in the previous Office Action, Paper No. 5, mailed October 6, 2003.

Rejections Repeated

35 U.S.C. §102(b)

Claim 14 has been rejected under 35 U.S.C. §102(b) as being anticipated by Bland et al. for the reasons previously of record in the action mailed 10/06/03. In that Office Action it was asserted that Bland et al. has a balloon for a medical device (angioplasty) which must inflate to a controlled size and should not stretch to a larger size, but cannot readily tear which is formed from tear resistant multilayer film comprising alternating layers of relatively stiff and ductile polymeric materials (col. 1, lines 10-50) which comprises more than 5 layers and therefore overlaps the claimed range of at least 7 up to 50 laminate layers (col. 3, lines 30-50).

Applicants maintain that claim 14 is patentable over Bland et al. for the reasons stated in the response mailed December 11, 2003. However, claim 14 has been amended to recite a balloon for a medical device comprising from 7 to 50 total polymer layers *alternating between layers composed of a compliant or semi-compliant polymer material and layers composed of a complaint or semi-compliant matrix polymer material and LCP.*

Support for the amendment is found to incorporate the limitations found in claim 15. Further support for the amendments to claim 14 is found on page 10, lines 3-10. No new matter has been added.

Bland et al. do not describe layers having such features.

Applicants respectfully request withdrawal of the rejection of claim 14 under 35 U.S.C. §102(b) as anticipated by Bland et al.

New Rejections

35 U.S.C. §103(a)

Rau et al. (WO 95/18647) in view of Zdrahala (US 5,248,305)

Claims 1-6 and 9-12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. (WO 95/18647) in view of Zdrahala (previously cited US 5,248,305). The Office Action asserts that Rau et al. has a balloon catheter (column 1, lines 1-5) which can be of integral catheter shaft/balloon construction (column 14, lines 1-5) comprising a plurality of fibers to provide reinforcement (column 8, lines 55-65).

Claim 1 of the present invention is directed to a balloon for a medical device comprising a *semi-compliant* polymer matrix material and a plurality of fibers distributed in the matrix material to provide reinforcement thereof, the fibers being distributed in a selected direction relative to the balloon axis and composed of material which has a greater tensile strength than the matrix material.

Support for this amendment can be found in the Brief Summary of the Invention, on page 4 in the Detailed Description, as well as on page 10. No new matter has been added.

Rau et al. disclose the incorporation of thermoplastic *polyimide* into various parts of balloon catheters such as catheter shafts and balloons (Abstract).

The shaft and/or balloon may be reinforced with a reinforcement material which may comprise various types of continuous or intermittent reinforcing components used in the composites of this invention. Among such suitable materials are continuous fiber or filament forms such as polyester, polyamide or carbon fiber, and further may be sphere and particulate forms such as glass. Reinforcing material may comprise glass, carbon, ceramic, fluoropolymer, graphite, liquid crystal polymers, polyester, polyamide, stainless steel, titanium and other metals such as nitinol, or radiopaque materials (such as Bismuth or Tungsten) and the like (col.8, lines 57-67).

Polyimides, being relatively inelastic and hard materials, are non-compliant polymeric materials. Applicants have enclosed a summary of physical properties for polyimide, available online from MatWeb, a copy of which is enclosed herewith. Compliance of balloon materials is discussed, for example, in commonly assigned U.S. Patent No. 5,556,383, a copy of

which is enclosed herewith.

The elongation at break for polyimide as found on page 2 of the polyimide overview is 4-10%. The hardness of polyimide, as measured using the Rockwell E hardness scale, is 50-99. The Rockwell hardness scales are employed for metals and for otherwise very hard materials while the Shore hardness scales are employed for polymeric materials. Applicants have included a summary from a website, http://www.machinist-materials.com/hardness.html, which shows a comparison of the various scales.

The properties of polyimide may be compared to polyethylene terephthalate, a non-compliant material, which has an elongation of 50% to 350% and a Rockwell Hardness of 110. A data sheet available online from MatWeb, has been enclosed herewith. See also commonly assigned U.S. Patent No. 5,556,383, enclosed herewith.

Rau et al. describe shafts and/or balloons into which is incorporated polyimide, a non-compliant balloon material.

Zdrahala describes extruded catheters and other flexible plastic *tubing* manufactured by extruding a tube of liquid crystal polymer plastic-containing material through a tube extrusion die. Zdrahala does not suggest further processing of the tubing to form balloons.

As all of the compositions for shafts and/or balloons suggested by Rau et al. incorporate polyimide, a non-compliant material, and Zdrahala makes no suggestion to further process their tubing into balloons, Applicants submit that the combination does not suggest a balloon formed with a semi-compliant polymer matrix material and a plurality of fibers as found in amended claim 1.

Claims 2-6 and 9-12 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable. Based on the foregoing, Applicants respectfully request withdrawal of the rejection of claims 1-6 and 9-12 under 35 U.S.C. §103(a) as being obvious over Rau et al., (WO 95/18647) and Zdrahala (US 5,248,305).

Rau et al. (WO 95/18647) in view of Zdrahala (US 5,248,305)
and Bland et al. (US 5,427,842)

Claims 7-8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Rau et al. (WO 95/18647) in view of Zdrahala (US 5,248,305)

And further in view of Bland et al. (previously cited US 5,427,842). The Office Action asserts that Rau et al. teaches the balloon may comprise a plurality of laminate layers (column 10, lines 10-20), at least one of which comprises said polymer matrix material and said fibers (reinforcing components) (column 14, lines 25-30), but fails to teach that the laminate layers comprise an alternating series of fiber-containing and fiber-free layers. The Office Action asserts that Bland et al. teaches that angioplasty balloons require stiff tear-resistant films since they cannot tear during use, and must inflate to a controlled size and should not stretch to a larger size (column 1, lines 45-50).

Applicants traverse the rejection.

Claim 7 depends from claim 6 which depends from claim 1. Claim 8 depends from claim 7. Claim 1 as amended, is now directed to a balloon comprising a semi-compliant polymer matrix material and a plurality of fibers distributed in the matrix material.

Rau et al. describe incorporation of polyimide into catheters/shafts as discussed above. Polyimide is non-compliant as discussed above.

Bland et al., as discussed in the previous response mailed December 11, 2003, describe a tear resistant film comprising more than five layers situated one on the other in a parallel array. The layers are individually selected from a stiff polyester or copolyester, a ductile polymeric material, and optionally, an intermediate material. The stiff polyester or copolyester is oriented in at least one direction. (Abstract).

Specifically, Bland et al. describe and claim the use of these films in ***security control laminates.*** Bland et al. mention angioplasty balloons, rather briefly, in the Background, but do not specifically teach making angioplasty balloons with the laminates described therein. Furthermore, even if they did, combining Bland et al. with Rau et al., does not lead one of skill in the art to a balloon comprising a semi-compliant polymer matrix material and a plurality of fibers distributed in the matrix material, as found in amended claim 1. Claims 7 and 8 depend from claim 1 and are patentable for at least the reasons that claim 1 is patentable. Applicants respectfully request withdrawal of the rejection of claims 7-8 under 35 U.S.C. §103(a) as being obvious over Rau et al. (WO 95/18647) in view of Zdrahala (US 5,248,305) and further in view of Bland et al. (US 5,427,842).

Bland et al. (US 5,247,842) in view of Rau et al. (WO 95/18647)

Claims 15-19 and 21 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bland et al. in view of Rau et al. The Office Action asserts that Bland et al. teaches that angioplasty balloons require stiff tear-resistant films since they cannot tear during use, and must inflate to a controlled size and should not stretch to a larger size (column 1, lines 45-50), but fails to teach that the stiff layers are composed of a blend of matrix polymer material and an LCP polymer.

Claim 1 as amended has been discussed above and is directed to a balloon comprising a semi-compliant polymer matrix material and a plurality of fibers distributed therein.

Rau et al. has been discussed above. Rau et al. describes incorporation of polyimide, a non-compliant polymer, into shafts and/or balloons. Thus the blend of non-compliant polyimide and LCP as referred to in the Office Action, is not the same as the semi-compliant polymer matrix material and fibers as found in amended claim 1 of the present invention.

Claim 14 has been amended to incorporate the limitations found in claim 15. Further support for the amendments to claim 14 is found on page 10, lines 3-10. No new matter has been added.

Claim 14 as amended is directed to a balloon for a medical device comprising from 7 to 50 total polymer layers alternating between layers composed of a compliant or semi-compliant polymer material and layers composed of a complaint or semi-compliant matrix polymer material and LCP.

Rau et al., as discussed above, fails to teach a compliant or semi-compliant polymer matrix material.

Consequently, providing the balloon of Rau et al. with 7-50 laminate layers comprising an alternating series of stiff fiber-containing and compliant fiber-free layers as taught by Bland et al., as asserted on page 7 in the last full paragraph of the Office Action, does not lead one of skill in the art to the balloon of claim 14. Claim 15 has been canceled. Claims 16-19 and 21 depend from claim 14 and are patentable for at least the reasons that claim 14 is patentable. Applicants respectfully request withdrawal of the rejection of claim 16-19 and 21 under 35

U.S.C. §103(a) as being obvious over Bland et al. in view of Rau et al.

Claims 20 and 22 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bland et al. in view of Rau et al. as applied to claims 15-17 and 21 above, and further in view of Zdrahala. The Office Action asserts that Bland et al. teaches a catheter balloon comprising at least 5 laminate layers of polymer material and that Rau et al. teaches a catheter balloon which has an integral balloon/shaft structure comprising alternating layers of single polymer and polymer/liquid crystal polymer fiber blend. The Office Action further asserts that both fail to teach the amount of liquid crystal polymer fiber, or that the polymer matrix is polyamide, but that Zdrahala teaches that the catheter tubing may be made out of 10 to 40 weight percent of liquid crystal polymer which overlaps the claimed range of from about 5 to about 25% by eight percent (claim 20), and that the compliant (softer) matrix polymer material may be polyamides (column 4, lines 20-30).

Claims 20 and 22 depend from claim 14 which has been amended and is discussed above.

Bland et al., Rau et al. and Zdrahala have also been discussed above.

Claims 20 and 22 are patentable for at least the reasons that claim 14 is patentable. Applicants respectfully request withdrawal of the rejection of claims 20 and 22 under 35 U.S.C. §103(a) as being unpatentable over Bland et al. in view of Rau et al. and further in view of Zdrahala.

CONCLUSION

Claims 1-14 and 16-23 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the examiner is invited to contact the attorney of record at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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